

Appl. No. 10/045,673

Response dated: March 31, 2005

Reply to Office Action of December 14, 2004

REMARKS

Claims 9-20 are pending in the application. Claims 1-8 and 21 were previously canceled in the amendment/response filed on September 20, 2004. Claims 9-20 are rejected. According to the final office action claims 22-40 were not entered as being drawn to a non-elected invention. However, since claims 22-29, as previously presented, depend from and specifically refer to elected claim 11, and therefore are encompassed by and within the invention recited in claim 11, applicants submit that claims 22-29 should be entered into the present case. Indeed, claims 27-29 each recite a particular species of peptide which is also recited in claim 11.

Applicants thank Examiners Teller and Tate for the telephonic interview of March 30, 2005, in which the final office action, the claims as presented in the amendment dated September 20, 2004, Figures 9 and 10, and Yamamoto were discussed.

In view of the above-described amendments and following remarks, reconsideration of claims 9-20, and consideration of previously presented claims 22-29 are respectfully requested.

§112 Rejections

Claims 11-20 are rejected under 35 USC §112, first paragraph, "because the specification while being enabling for activated form of vitamin D binding protein (ADBP) and fADBP (SEQ ID NO:1) does not reasonably provide enablement for one or more DBP peptides and combinations thereof." (See last paragraph on page 2 of the Office Action.)

Claim 9, as previously presented, recites a method of increasing bone density in a subject in need of the same by administering ADBP. As the Patent Office has stated, such method is enabled. Claims 17-20 depend from claim 9, and are also enabled.

Claim 11, as previously presented, recites a method of increasing bone density in a subject in need of the same by administering a peptide comprising the first 3, 4, 5, 6, 7, 8, 10, 11, 12, 13, or 14 amino acids of SEQ ID NO. 1. The present application provides sufficient guidance for one of ordinary skill in the art to make such peptides. Moreover, the present application shows that administration of such peptides increases total bone density, trabecular bone density, or cortical bone density in newborn or adult rats. (See Figures 2, 8, 9, 10, 11, and 12 of the present application.) Accordingly, applicants submit that claim 11 is fully enabled.

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Previously presented claims 12-16 depend from claim 11, and are for the same reason also enabled.

Accordingly, Applicants request withdrawal of the §112 rejection of claim 9-20 and entry of claims 22-29 which depend from enabled claim 11..

§ 103 Rejections

Claims 9-20 are rejected as being unpatentable over Yamamoto (USPN 6,410,269) (hereinafter "Yamamoto").

Claim 9, as previously presented, recites a method of increasing bone density in a subject in need of the same by administering ADBP to the subject, and claim 11, as previously presented, recites a method of increasing bone density in a subject in need of the same by administering a peptide that comprises the first 3-8 or 10-14 amino acids of SEQ ID NO. 1 to the subject. Yamamoto neither teaches nor suggests such a method. Yamamoto recites that the recombinant protein and specific peptide taught therein "are to be used for therapy of cancer, HIV-infection and osteopetrosis". Thus, the only bone disorder mentioned in Yamamoto is osteopetrosis, a condition which, according to Yamamoto, is "characterized by an excess accumulation of bone throughout the skeleton..." (See column 4, lines 41-42 of Yamamoto.). Because they have excess bone, patients with osteopetrosis are not in need of a therapy that increases bone density. Such patients are in need of a therapy that causes "resorption of the excess skeletal matrix." (See column 5, line 3 of Yamamoto, emphasis added) . Thus, Yamamoto would not motivate one of ordinary skill in the art to treat a patient who has systemic or localized bone loss, and thus needs a therapy that increases bone density, with the recombinant vitamin D binding protein recited in Yamamoto or any fragment thereof. Lacking such motivation, Yamamoto does not render claims 9 or 11, or claims 10 and 12-29, all of which depend from claim 9 or claim 11 obvious.

Moreover, Applicants also note that the only peptide disclosed in Yamamoto column 2, lines 4-7 and column 8, lines 46-49 is the 89 amino acid fragment which forms domain III of vitamin D binding protein (See Figure 5, column 2 lines 4-6, and column 11, 40-51 of Yamamoto)). For this additional reason, Yamamoto does not render the method recited in claims 11 or the claims that depend therefrom obvious.

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Accordingly, applicants submit that claims 9-20 and claims 22-29, all of which depend from claim 11, are patentable over Yamamoto, and that the rejection should be withdrawn.

In view of the above-described amendments and remarks, applicants submit that claims 9-20 are allowable. Applicants also submit that claims previously presented claims 22-29, all of which depend from claim 11 should be entered, and are also allowable. Prompt notice of such allowance is respectfully requested. If the Examiner feels that further changes to the application are necessary or if he has any questions regarding the amendments or new claims, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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